

Claims

1. A process for purifying on a large scale a product from a feedstock containing one or more impurities having closely-related physical properties to the product, which process comprises

feeding the feedstock into an extraction column under conditions adapted for separating more- or less-polar impurities from the feedstock, wherein a lighter phase flows counter to a heavier phase, thereby forming an output in one phase containing the product containing less more- or less-polar impurities so that the output contains the product in a substantially purified form, and wherein the lighter phase comprises heptane and acetone or heptane and isopropanol, the heavier phase comprises water and acetone or water and isopropanol, and the product is a cyclosporin, a rapamycin or an ascomycin.

2. A process as claimed in claim 1, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone, or about 90 wt-% n-heptane and about 10 wt-% isopropanol.

3. A process as claimed in claim 1, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone, or about 68 wt-% water and about 32 wt-% isopropanol.

4. A process for purifying on a large scale a product from a feedstock containing one or more impurities having closely-related physical properties to the product, which process comprises the steps of

a) feeding the feedstock into a first extraction column under conditions adapted for separating more- or less-polar impurities from the feedstock, wherein a lighter phase flows counter to a heavier phase, thereby forming a first output in one phase containing the product containing less more- or less-polar impurities, and

b) feeding the first output into a second extraction column under conditions adapted for separating less- or more-polar impurities respectively from the first output, wherein the lighter phase flows counter to the heavier phase, thereby forming in one phase a second output, so that the second output contains the product in a substantially purified form, wherein the lighter phase comprises heptane and acetone or heptane and isopropanol, the heavier phase

comprises water and acetone or water and isopropanol, and the product is a cyclosporin, a rapamycin or an ascomycin.

5. A process as claimed in claim 4, wherein the lighter phase comprises about 25 wt-% n-heptane and about 75 wt-% acetone, or about 90 wt-% n-heptane and about 10 wt-% isopropanol.

6. A process as claimed in claim 4, wherein the heavier phase comprises about 50 wt-% water and about 50 wt-% acetone, or about 68 wt-% water and about 32 wt-% isopropanol.

7. A process as claimed in claim 1 or claim 4, wherein the product is Cyclosporin A, Cyclosporin D or a derivative thereof, Cyclosporin G or a derivative thereof, rapamycin, 40-O-(2-hydroxy)ethyl rapamycin, ascomycin, 33-epi-chloro-33-desoxyascomycin, or FK506.

8. A countercurrent extraction column having between 100 and 200 compartments, and an overall efficiency of about 10 to 30 %.

9. A bulk quantity of cyclosporin A with an impurity level of less than 0.5% by area using HPLC.

10. A composition comprising as active agent cyclosporin A as claimed in claim 9.